Food and Drug Administration, Center for Biologics Evaluation and Research
Vaccines and Related Biological Products Advisory Committee Meeting
July 23, 2009
Hilton Hotel, Washington DC North/Gaithersburg
Montgomery Ballroom
620 Perry Parkway, Gaithersburg, MD 20877
DRAFT AGENDA

Open Session

Discussion of clinical trials to support use of vaccines against the 2009 H1N1 influenza virus

8:00 a.m.	Call to Order and Opening Remarks	John Modlin, M.D., Chair
8:05	Conflict of Interest Statement	Christine Walsh, R.N., FDA
8:15	FDA Introduction	Norman Baylor, Ph.D., FDA
8:20	Epidemiology of Newly Emerged H1N1 Influenza Virus/Strain Selection	Anthony Fiore, M.D., MPH, CDC Nancy Cox, Ph.D., CDC
8:50	Overview of DHHS Procurement of H1N1 Influenza Vaccines & Adjuvants	Robin Robinson, Ph.D., DHHS
9:05	Questions/Clarifications	
9:15	Manufacturing Considerations	Jerry Weir, Ph.D., FDA
9:30	FDA Regulatory Approaches & Activities to Support Use of H1N1 Vaccine	Wellington Sun, M.D., FDA
9:45	Overview of Clinical Studies by NIAID/NIH	Linda Lambert, Ph.D., NIH
10:00	Questions/Clarifications	
10:10	Break	
10:30	Post Marketing Safety Monitoring During an Influenza Pandemic/Post Marketing Collection of Effectiveness Data	Hector Izurieta, M.D., MPH, FDA
11:00	Questions/Clarifications	

11:10	Manufacturers Comments on Clinical Trials with H1N1 Vaccine	Vaccine Manufacturers: Novartis, Sanofi Pasteur, CSL Ltd., MedImmune, GlaxoSmithKline
12:00 p.m.	Lunch	
1:00	Open Public Hearing	
2:00	Presentation of Issues to be Discussed	Wellington Sun, M.D., FDA
2:05	Committee Discussion	
4:00	Adjourn Meeting	